ARC 0365C

PUBLIC HEALTH DEPARTMENT[641]

Adopted and Filed

Pursuant to the authority of Iowa Code sections 135.11 and 125.7, the Department of Public Health hereby amends Chapter 155, "Licensure Standards for Substance Abuse and Problem Gambling Treatment Programs," Iowa Administrative Code.

The rules in Chapter 155 describe licensure standards for substance abuse and problem gambling treatment programs. These amendments replace current language which requires that all client/patients admitted to residential, inpatient or halfway house services and high-risk outpatient client/patients have a tuberculin skin test, simplify some requirements and remove the requirement to test high-risk outpatient client/patients. These amendments add a requirement that residential, inpatient or halfway house staff have a tuberculin skin test. To protect the health and safety of Iowans, these changes will bring Iowa into compliance with tuberculosis-testing recommendations from the United States Centers for Disease Control and Prevention (CDC) in this area.

The Iowa Administrative Code currently requires employees in the following areas to be screened for tuberculosis (TB): child care centers, hospitals, nursing facilities, residential care facilities for persons with mental illness, intermediate care facilities for persons with mental illness and residential care facilities for the intellectually disabled.

The amendment in Item 1 rescinds the paragraph that requires all client/patients admitted to residential, inpatient or halfway house services and high-risk outpatient client/patients to have a tuberculosis skin test.

The amendment in Item 2 adopts a new heading to precede the rules pertaining to tuberculosis screening of substance abuse and problem gambling treatment program health care workers and residents.

The amendment in Item 3 adopts new definitions and rules regarding tuberculosis screening of substance abuse and problem gambling treatment program health care workers and residents.

Notice of Intended Action was published in the July 25, 2012, Iowa Administrative Bulletin as **ARC 0227C**. One written comment was received, in addition to a comment from a Board member during the State Board of Health meeting on July 11, 2012. The written comment referred to the "extremely technical" language in the amendment. In response to this comment, the Department will develop a list of Frequently Asked Questions (FAQ) regarding the amendment. As a result of the other comment, two additions were made to the amendments as published under Notice of Intended Action. A definition of "Bacille Calmette-Guerin (BCG) vaccination" has been added in rule 641—155.37(125,135) and paragraph "g" has been added in subrule 155.38(3).

The State Board of Health adopted these amendments on September 12, 2012.

After analysis and review of this rule making, no impact on jobs has been found.

These amendments are intended to implement Iowa Code sections 125.15, 125.17, 125.32 and 135.150.

These amendments will become effective on November 7, 2012.

The following amendments are adopted.

ITEM 1. Rescind paragraph **155.21(16)"d."**

ITEM 2. Adopt the following **new** heading to precede rule 641—155.36(125,135):

TUBERCULOSIS (TB) SCREENING:
HEALTH CARE WORKERS AND RESIDENTS

ITEM 3. Adopt the following **new** rules 641—155.36(125,135) to 641—155.38(125,135):

641—155.36(125,135) Purpose. The purpose of these rules is to outline procedures for conducting tuberculosis (TB) screening for health care workers and residents at substance abuse and problem gambling treatment program facilities. Facilities will need to conduct a risk assessment to determine

the risk classification of the facility and to identify appropriate screening criteria. The screening criteria are consistent with those of the U.S. Centers for Disease Control and Prevention (CDC), TB Elimination Division, as outlined in the MMWR December 30, 2005/Vol. 54/No. RR-17, "Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Settings, 2005."

641—155.37(125,135) Definitions. For the purpose of these rules, the following definitions shall apply:

"Bacille Calmette-Guerin (BCG) vaccination" means a vaccine for TB. BCG is used in many countries with a high prevalence of TB to prevent childhood tuberculosis meningitis and military disease. BCG is not generally recommended for use in the United States because of the low risk of infection with *Mycobacterium tuberculosis*, the variable effectiveness of the vaccine against adult pulmonary TB, and the vaccine's potential interference with tuberculin skin test reactivity.

"Baseline TB screening" means the screening of staff and residents for latent tuberculosis infection (LTBI) and TB disease at the beginning of employment or upon admission to a facility. Baseline TB screening includes a symptom screen for all staff and residents, and tuberculin skin tests (TSTs) or interferon-gamma release assay (IGRA) for *Mycobacterium tuberculosis* for those staff and residents with previous negative test results for *M. tuberculosis* infection.

"Baseline TST" or *"baseline IGRA"* means the TST or IGRA, respectively, that is administered at the beginning of employment to newly hired staff or upon admission to residents of facilities.

"Boosting" means a phenomenon in which a person has a negative TST (i.e., false-negative) result years after infection with *M. tuberculosis* and then a positive subsequent TST result. The positive TST result is caused by a boosted immune response of previous sensitivity rather than by a new infection (false-positive TST conversion). Two-step testing reduces the likelihood of mistaking a boosted reaction for a new infection.

"Extrapulmonary TB" means TB disease in any part of the body other than the lungs (e.g., kidney, spine, or lymph nodes).

"Interferon-gamma release assay" or *"IGRA"* means a whole-blood test that can aid in diagnosing *Mycobacterium tuberculosis* infection.

"Laryngeal TB" means a form of TB disease that involves the larynx and may be highly infectious.

"Latent TB infection" or *"LTBI"* means infection with *M. tuberculosis* without symptoms or signs of disease having manifested.

"Mantoux method" means a skin test performed by intradermally injecting 0.1 mL of purified protein derivative (PPD) tuberculin solution into the volar or dorsal surface of the forearm.

"Pulmonary TB" means TB disease that occurs in the lung parenchyma, usually producing a cough that lasts greater than three weeks. Pulmonary TB is usually infectious.

"Purified protein derivative (PPD) tuberculin" means a material used in diagnostic tests for detecting infection with *M. tuberculosis*.

"Risk classification" means the category the infection control team, or designated other, determines that the setting's TB risk classification is based, as a result of the TB risk assessment.

"Serial screening" refers to TB screening performed at regular intervals following baseline TB screening. Serial TB screening, also called annual or ongoing TB testing, consists of two components: (1) assessing for current symptoms of active TB disease, and (2) testing for the presence of infection with *M. tuberculosis* by administering either a TST or single IGRA.

"Symptom screen" means a procedure used during a clinical evaluation in which patients are asked if they have experienced any departure from normal in function, appearance, or sensation related to TB disease (e.g., cough).

"TB patient" means a person who had undiagnosed infectious pulmonary or laryngeal TB while in the facility during the preceding year. "TB patient" does not include persons with LTBI (treated or untreated), extrapulmonary TB disease, pulmonary, or laryngeal TB that have met criteria for noninfectiousness.

"TB risk assessment" means an initial and ongoing evaluation of the risk for transmission of *M. tuberculosis* in a particular health care setting.

"TB screening" means an administrative control measure in which evaluation for LTBI and TB disease is performed through baseline and serial screening of staff and residents of facilities.

"TB screening plan" means a plan that facilities develop and implement that comprises four major components: (1) baseline testing for *M. tuberculosis* infection, (2) serial testing for *M. tuberculosis* infection, (3) serial screening for signs or symptoms of TB disease, and (4) TB training and education.

"Treatment for LTBI" means treatment that prevents the progression of *M. tuberculosis* infection into TB disease.

"Tuberculin skin test" or *"TST"* means a diagnostic aid for finding *M. tuberculosis* infection. The Mantoux method is the recommended method to be used for the TST.

"Tuberculosis" or *"TB"* means the namesake member organism of *M. tuberculosis* complex and the most common causative infectious agent of TB disease in humans. In certain instances, the species name refers to the entire *M. tuberculosis* complex, which includes *M. bovis* and *M. african*, *M. microti*, *M. canetti*, *M. caprae*, and *M. pinnipedii*.

"Tuberculosis disease" or *"TB disease"* means a condition caused by infection with a member of the *M. tuberculosis* complex that has progressed to causing clinical (manifesting symptoms or signs) or subclinical (early stage of disease in which signs or symptoms are not present, but other indications of disease activity are present) illness.

"Two-step tuberculin skin test" or *"two-step TST"* means the procedure used for the baseline skin testing of persons who will receive serial TSTs to reduce the likelihood of mistaking a boosted reaction for a new infection.

641—155.38(125,135) Tuberculosis screening of staff and residents.

155.38(1) *TB risk assessment.* Annually, each facility shall conduct a TB risk assessment to evaluate the risk for transmission of *M. tuberculosis*, regardless of whether a person with suspected or confirmed TB disease is expected to be encountered in the facility. The TB risk assessment shall be utilized to determine the types of administrative, environmental, and respiratory protection controls needed and serves as an ongoing evaluation tool of the quality of TB infection control and for the identification of needed improvements in infection control measures. The risk assessment shall include:

a. The community rate of TB,

b. The number of persons with infectious TB encountered in the facility, and

c. The speed with which persons with infectious TB are suspected, isolated, and evaluated to determine if persons with infectious TB exposed staff or others in the facility. TB cases include persons who had undiagnosed infectious pulmonary or laryngeal TB while in the facility during the preceding year. This does not include persons with LTBI (treated or untreated), persons with extrapulmonary TB disease, or persons with pulmonary and laryngeal TB that have met criteria for noninfectiousness.

155.38(2) *Facility risk classification.* The infection control team or designated staff in a facility is responsible for determining the type of risk classification of the facility. The facility risk classification is used to determine the frequency of TB screening. The facility risk classification may change due to an increase or decrease in the number of TB cases during the preceding year.

a. Types of risk classifications.

(1) "Low risk" means that a facility is one in which persons with active TB disease are not expected to be encountered and in which exposure to TB is unlikely.

(2) "Medium risk" means that a facility is one in which health care workers will or might be exposed to persons with active TB disease or to clinical specimens that might contain *M. tuberculosis*.

(3) "Potential ongoing transmission" means that a facility is one in which there is evidence of person-to-person transmission of *M. tuberculosis*. This classification is a temporary classification. If it is determined that this classification applies to a facility, the facility shall consult with the department's TB control program.

b. Classification criteria—low risk.

(1) Inpatient settings with 200 or more beds: If a facility has fewer than six TB patients for the preceding year, the facility shall be classified as low risk.

(2) Inpatient settings with fewer than 200 beds: If a facility has fewer than three TB patients for the preceding year, the facility shall be classified as low risk.

(3) Outpatient, outreach, and home-based health care settings: If a facility has fewer than three TB patients for the preceding year, the facility shall be classified as low risk.

c. Classification criteria—medium risk.

(1) Inpatient settings with 200 or more beds: If a facility has six or more TB patients for the preceding year, the facility shall be classified as medium risk.

(2) Inpatient settings with fewer than 200 beds: If a facility has three or more TB patients for the preceding year, the facility shall be classified as medium risk.

(3) Outpatient, outreach, and home-based health care settings: If a facility has three or more TB patients for the preceding year, the facility shall be classified as medium risk.

d. Classification criteria—potential ongoing transmission. If evidence of ongoing *M. tuberculosis* transmission exists at a facility, the facility shall be classified as potential ongoing transmission, regardless of the facility's previous classification.

155.38(3) *Baseline TB screening procedures for facilities.*

a. All facility staff members shall receive baseline TB screening upon hire. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis*.

b. A staff member may begin working with clients or residents after a negative TB symptom screen (i.e., no symptoms of active TB disease) and a negative TST (i.e., first step) or negative IGRA. The second TST may be performed after the staff member starts working with clients or residents.

c. A staff member with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician. Treatment for LTBI should be considered in accordance with CDC guidelines.

d. A staff member with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, does not need another chest radiograph at the time of hire.

e. TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for staff with a documented history of TB disease, documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., interferon-gamma (IFN-g)). All other staff should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

f. A second TST is not needed if the staff member has a documented TST result from any time during the previous 12 months. If a newly employed staff member has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

g. Previous BCG vaccination is not a contraindication to having an IGRA, a TST or two-step skin testing administered. Health care workers with previous BCG vaccination should receive baseline and serial testing in the same manner as those without BCG vaccination. Evaluation of TST reactions in persons vaccinated with BCG should be interpreted using the same criteria for those not BCG-vaccinated. A health care worker's history of BCG vaccination should be disregarded when administering and interpreting TST results. Prior BCG vaccination does not cause a false-positive IGRA test result.

155.38(4) *Serial TB screening procedures for facilities.*

a. Facilities classified as low risk. After baseline testing of staff for infection with *M. tuberculosis*, additional TB screening of staff is not necessary unless an exposure to *M. tuberculosis* occurs.

b. Facilities classified as medium risk.

(1) After undergoing baseline testing for infection with *M. tuberculosis*, staff should receive TB screening annually (i.e., symptom screen for all staff members and testing for infection with *M. tuberculosis* for staff members with baseline negative test results).

(2) Staff members with a baseline positive or new positive test result for *M. tuberculosis* infection or documentation of previous treatment for LTBI or TB disease shall receive one chest radiograph result to exclude TB disease. Instead of participating in serial testing, staff should receive a symptom screen annually. This screen should be accomplished by educating the staff about symptoms of TB disease and instructing the staff members to report any such symptoms immediately to the occupational health unit. Treatment for LTBI should be considered in accordance with CDC guidelines.

c. Facilities classified as potential ongoing transmission. Testing for infection with *M. tuberculosis* may need to be performed every eight to ten weeks until lapses in infection control have been corrected and no additional evidence of ongoing transmission is apparent. The potential ongoing transmission classification should be used only as a temporary classification. This classification warrants immediate investigation and corrective steps. After a determination that ongoing transmission has ceased, the setting shall be reclassified as medium risk for a minimum of one year.

155.38(5) *Screening of staff who transfer to other facilities.*

a. Staff transferring from a low-risk facility to another low-risk facility. After a baseline result for infection with *M. tuberculosis* is established and documented, serial testing for *M. tuberculosis* infection is not necessary for staff transferring from a low-risk facility to another low-risk facility.

b. Staff transferring from a low-risk facility to a medium-risk facility. After a baseline result for infection with *M. tuberculosis* is established and documented, annual TB screening, including a symptom screen and TST or IGRA for persons with previously negative test results, should be performed for staff transferring from a low-risk facility to a medium-risk facility.

155.38(6) *Baseline TB screening procedures for residents of residential, inpatient, and halfway house facilities.*

a. TB screening is a formal procedure to evaluate residents for LTBI and TB disease. Baseline TB screening consists of two components: (1) assessing for current symptoms of active TB disease and (2) using a two-step TST or a single IGRA to test for infection with *M. tuberculosis.*

b. All residents shall be assessed for current symptoms of active TB disease upon admission. Within 72 hours of a resident's admission, baseline TB testing for infection shall be initiated unless baseline TB testing occurred within three months prior to the resident's admission.

c. Residents with a new positive test result for *M. tuberculosis* infection (i.e., TST or IGRA) shall receive one chest radiograph result to exclude TB disease. Repeat radiographs are not needed unless symptoms or signs of TB disease develop or unless recommended by a clinician.

d. Residents with documentation of past positive test results (i.e., TST or IGRA) and documentation of the results of a chest radiograph indicating no active disease, dated after the date of the positive TST or IGRA test result, do not need another chest radiograph at the time of admission.

e. TB, TST or IGRA tests for *M. tuberculosis* infection do not need to be performed for residents with a documented history of TB disease, a documented previously positive test result for *M. tuberculosis* infection, or documented completion of treatment for LTBI or TB disease. Documentation of a previously positive test result for *M. tuberculosis* infection can be substituted for a baseline test result if the documentation includes a recorded TST result in millimeters or IGRA result, including the concentration of cytokine measured (e.g., IFN-g). All other residents should undergo baseline testing for *M. tuberculosis* infection to ensure that the test result on record in the setting has been performed and measured using the recommended diagnostic procedures.

f. A second TST is not needed if the resident has a documented TST result from any time during the previous 12 months. If a new resident has had a documented negative TST result within the previous 12 months, a single TST can be administered in the new setting. This additional TST represents the second stage of two-step testing. The second test decreases the possibility that boosting on later testing will lead to incorrect suspicion of transmission of *M. tuberculosis* in the setting.

g. After baseline TB screening is accomplished, serial TB screening of the residents is not recommended.

155.38(7) *Serial TB screening procedures for residents of residential, inpatient, and halfway house facilities.*

a. If a resident is discharged and readmitted to a facility and less than 12 months have passed since the last TB screening, residents should receive a symptom screen upon readmittance. This screen should be accomplished by educating the resident about symptoms of TB disease and instructing the resident to report any such symptoms immediately to the infection control team or designated other staff. If symptoms or signs of TB disease are documented, then a medical evaluation to include a chest X-ray to rule out TB disease is required.

b. If a resident is discharged and readmitted to a facility and more than 12 months have passed since the last TB screening, baseline TB screening should be repeated as outlined in subrule 155.38(6).

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